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Due Process Supreme Court Appellate Division

SUPREME COURT, APPELLATE DIVISION

FIRST DEPARTMENT

T.D. v. New York State Office of Mental Health[158] (decided Dec. 5, 1996)

Plaintiffs brought this action against defendant, New York State Office of Mental Health [hereinafter "OMH"], to challenge the constitutionality of defendant's regulations for acquiring consent in human subject research under both the Federal[159] and New York State[160] Constitutions.[161] The Appellate Division, First Department, affirmed the decision of the Supreme Court of the State of New York and held that OMH's failure "to provide adequate notice and review procedures" not only violated the Federal and New York State Constitutions, but common law and numerous health and social services laws as well.[162]

OMH is charged with promulgating and enforcing regulations for patients who are involuntarily mentally institutionalized and "adjudicated mentally incapable of giving or withholding informed consent."[163] The OMH's stated "purpose is to ensure the protection of patients who participate in research while, at the same time, facilitating research into the very disorders from which they suffer and which underlie their impairment."[164] When patients participate in these types of research projects, OMH must provide adequate practices for determining mental

158. 650 N.Y.S.2d 173 (1st Dep't 1996).

159. U.S. CONST. amend. XIV. The Fourteenth Amendment provides in pertinent part: "[N]or shall any State deprive any person of life, liberty, or property without due process of law . . . ." *Id.*

160. N.Y. CONST. art. I, § 6. This provision provides in pertinent part: "No person shall be deprived of life, liberty, or property without due process of law." *Id.*

161. *T.D.*, 650 N.Y.S.2d at 186-87.

162. *Id.* at 194.

163. *Id.* at 177.

164. *Id.* at 175 (quoting N.Y. COMP. CODES R. & REGS. tit. 14, § 527.10(b) (1995)).

capacity and obtaining consent.[165] At the very least, OMH must provide adequate constitutional safeguards for the patients who may be potential subjects of these research projects.[166] Specifically, the focus in this case was on patients who were "children and adults deemed incapable of giving or withholding consent for participation in experiments involving more than minimal risk."[167]

The Appellate Division, First Department, responded to plaintiffs' contention that they are protected under the United States Constitution, more specifically the Fourteenth Amendment Due Process Clause.[168] The Appellate Division observed that the United States Supreme Court addressed the issue of whether an incarcerated inmate may be forced, without his consent, into taking anti-psychotic medication. In the landmark case of *Washington v. Harper*,[169] relied on by the appellate division, the United States Supreme Court held that a prison inmate does not surrender his due process rights even though he may be

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165. *Id.* at 185. The requisite capacity necessary for a patient to validly consent to medical treatment is defined as "the patient's ability to understand the purpose, nature, risks, benefits and alternatives (including non-participation) of the research, to make a decision about participation, and to understand that decision about participation in the research will involve no penalty or loss of benefits to which the patient is otherwise entitled." N.Y. COMP. CODES R. & REGS. tit. 14, § 527.10(c)(2) (1995).

166. *T.D.*, 650 N.Y.S.2d at 185 (noting that especially when experiments offer little or no benefit to the patient, informed consent must be obtained). *See* N.Y. PUB. HEALTH LAW § 2442 (McKinney 1993). This section provides in part that "[n]o human research may be conducted in this state in the absence of the voluntary informed consent subscribed to in writing by the human subject." *Id.*

167. *T.D.*, 650 N.Y.S.2d at 185.

168. *Id.* at 186.

169. *T.D.*, 650 N.Y.S.2d at 186. *See* Washington v. Harper, 494 U.S. 210 (1990). In *Washington*, an inmate was incarcerated in a state penitentiary where he acquiesced to the administration of anti-psychotic medication. *Id.* at 213. When respondent later refused to continue the treatment, the state sought to medicate him over his objection. *Id.* The Court held that the prison's procedures of providing medical treatment were constitutionally within the requirements of due process largely due to the presence of "notice, right to be present at an adversary hearing, and the right to present and cross-examine witnesses." *Id.* at 235.

incarcerated.[170] More specifically, an inmate retains the right to refuse the administration of anti-psychotic medication.[171] The Court, however, carved out the following two exceptions for situations in which a mentally ill inmate may have to submit to treatment of anti-psychotic drugs against his will: (1) where the prisoner represents a danger to himself or to others; and (2) where the treatment is in the prisoner's best interest.[172] More importantly, the Court recognized the importance of adequate hearing procedures established by correction officials.[173] The Court determined that in order for a prison to administer anti-psychotic medication to an inmate against his will, it must fulfill numerous substantive and procedural processes established to protect the constitutional right of the prisoner.[174] Two years later, in *Riggins v. Nevada,*[175] the Supreme Court reaffirmed its previous decision in *Washington* by holding that "forcing anti-psychotic drugs on a convicted prisoner is impermissible absent a

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170. *Id.* at 229.

171. *Id.* The Court stated that "[t]he forcible injection of medication into a non-consenting person's body represents a substantial interference with that person's liberty." *Id.* (citations omitted).

172. *Id.* at 227.

173. *Id.* at 233. "A State's attempt to set a high standard for determining when involuntary medication with anti-psychotic drugs is permitted cannot withstand [a constitutional] challenge if there are no procedural safeguards to ensure the prisoner's interests are taken into account." *Id.*

174. *Id.* at 227.

175. 504 U.S. 127 (1992). In *Riggins*, petitioner was prescribed anti-psychotic drugs while awaiting trial for murder. *Id.* at 129. After he was adjudicated as being mentally competent to stand trial, he submitted a motion to the court requesting that his medication be suspended during the course of the trial, based on the assertion that the Fourteenth Amendment "infringed upon his freedom and that the drugs' effect on his demeanor and mental state during the trial would deny him due process." *Id.* at 130. Petitioner's motion was denied and he was convicted of murder and robbery and sentenced to death. *Id.* at 131. The Nevada Supreme Court affirmed the conviction and petitioner appealed. *Id.* at 132. The United States Supreme Court reversed and held that a due process violation occurs when a "record contains no finding that might support a conclusion that administration of anti-psychotic medication was necessary to accomplish an essential state policy . . . ." *Id.* at 138.

finding of overriding justification and a determination of medical appropriateness."[176]

Relying on the Court's previous decisions in *Washington* and *Riggins*, the Appellate Division, First Department, stated that in order for the New York State regulations to withstand constitutional scrutiny, they must, at a minimum, provide the patient with specific provisions for notice.[177] Therefore, an evaluation must be conducted in order to determine the patient's mental capacity coupled with appropriate administrative and judicial review procedures established to determine the requisite capacity.[178] The key to determining capacity, or lack thereof, is central in determining whether a patient must submit to the medical research.[179] The Institutional Review Board [hereinafter "IRB"] is charged with the responsibility of reviewing consent procedures and determining a patient's requisite mental capacity to consent.[180]

However, constitutional problems arise when the IRB, regardless of whether a patient may lack capacity to give an informed consent, "has the authority to require that an assessment of the patient[s] capacity be made by a person or persons who are not affiliated with the research and/or who have specific qualifications and/or certifications."[181] Specifically, the IRB may override a patient's consent if it determines that there are direct health benefits to the patient available only through this type of medical research.[182] Where capacity is not present, the IRB may obtain two independent evaluations of capacity of consent.[183] The independent evaluations are then submitted to

176. *Id.* at 135.
177. *T.D.*, 650 N.Y.S.2d at 187.
178. *Id.*
179. *Id.*
180. *Id.*
181. N.Y. COMP. CODES R. & REGS. tit. 14, § 527.10(e)(2)(ii) (1995).
182. N.Y. COMP. CODES R. & REGS. tit. 14, 527.10(d)(6). This section provides in pertinent part: "[R]esearch which involves patients who lack the capacity to consent may not be approved unless the IRB has determined and documented . . . . [that it] involves no more than minimal risk and/or invasive procedures . . . . " *Id.*
183. *T.D.*, 650 N.Y.S.2d at 188.

the clinical director who makes the final determination of the patient's capacity.[184] Once the patient is adjudicated to be incapable of consenting to the treatment, consent may be obtained by a wide range of other people.[185]

The *T.D.* court found that the above mentioned procedural safeguards do not adequately protect the patient's due process and privacy rights guaranteed by the Fourteenth Amendment of the Federal Constitution.[186] Specifically, the court made the following findings:

> The regulations do not identify or set out specific or even minimum qualifications for the individual or individuals who initially access a potential subject's capacity . . . .[T]here are no provisions requiring any notice to the patient that his or her capacity to provide or withhold consent for a particular study is being questioned . . . . [and] there is no provision for review of a determination of lack of capacity at the patient's request.[187]

In addition, a patient's request to review the decision of his or her mental capacity and the surrogate's approval of the medical treatment and is not likely to be reviewed.[188]

Turning to the New York State Constitution, the Appellate Division, First Department relied on the principal case of *Rivers v. Katz*[189] which held that the Due Process Clause of

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184. *Id.*

185. *Id. See generally*, N.Y. COMP. CODES R. & REGS. tit. 14, § 527.10(e)(2)(iii)(a) (1995) (providing for designation of a party pursuant to a durable power of attorney); N.Y. COMP. CODES R. & REGS. tit. 14, § 527.10(e)(2)(iv) (1995) (providing for consent to be obtained from a parent, spouse, adult child, sibling); N.Y. COMP. CODES R. & REGS. tit. 14, § 527.10(c)(3) (1995) (providing that consent can be obtained from a close friend); N.Y. COMP. CODES R. & REGS. tit. 14, § 527.10(e)(3)(i) (1995) (providing in the case of minors, consent is to be obtained from a parent or legal guardian or, in the absence of such person, an adult relative qualified to make medical treatment decisions for the minor).

186. *T.D.*, 650 N.Y.S.2d at 189.

187. *Id.*

188. *Id.* at 190.

189. 67 N.Y.2d 485, 495 N.E.2d 337, 504 N.Y.S.2d 74 (1986). In *Rivers*, the New York Court of Appeals addressed the issue of whether involuntarily committed mental patients have a protected constitutional right to refuse anti-

the New York State Constitution guarantees the fundamental right of involuntarily committed mental patients to refuse medication.[190] In *Katz*, the New York Court of Appeals reaffirmed its decision in *In Re Storar*[191] which held that an individual has a common law right to refuse medical treatment, irrespective of whether such treatment is vital to survival.[192] However, the *Rivers* court limited the circumstances under which the state's police power would justify forced medication to times of imminent danger to the patient themselves, or to others, or when a compelling state interest is present.[193] State interests unrelated to the patient's safety or the safety of others could not outweigh the patient's fundamental right to refuse medication.[194]

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psychotic medication. *Id.* at 489-90, 495 N.E.2d at 339, 504 N.Y.S.2d at 76. The court determined that involuntary commitment is not a sufficient basis to assume that the patient is incapable of making a reasoned decision regarding their physical condition. *Id.* at 493-94, 495 N.E.2d at 341-42, 504 N.Y.S.2d at 79. Therefore, a patient is entitled to a hearing to determine mental capacity and prior involuntary medical treatment. *Id.* at 497, 495 N.E.2d at 344, 504 N.Y.S.2d at 81. The court reasoned that the patient's desires must be respected "in order to insure that the greatest possible protection he is accorded is autonomy and freedom from unwanted interference with the furtherance of his own desires." *Id.* at 493, 495 N.E.2d at 341, 504 N.Y.S.2d at 78.

190. *Id.* at 492, 495 N.E.2d at 341, 504 N.Y.S.2d at 78 ("[E]very individual 'of adult years and sound mind has a right to determine what shall be done with his own body.'") (quoting Schloendorff v. Society of N.Y. Hosp., 211 N.Y. 125,129, 105 N.E. 92, 93 (1914)).

191. 52 N.Y.2d 363, 420 N.E.2d 64, 438 N.Y.S.2d 266 (YEAR) (stating that where a state has a "legitimate interest in protecting the lives of its citizens," the common law right to refuse medical treatment should yield to the legitimate state interest), *cert. denied*, 454 U.S. 858 (1981).

192. *Id.* at 377, 420 N.E.2d at 71, 438 N.Y.S.2d at 273.

193. *Rivers*, 67 N.Y.2d at 492, 495 N.E.2d at 341, 504 N.Y.S.2d at 78. The court went further and rejected "[a]ny implication that State interests unrelated to the patient's well-being or those around him can outweigh his fundamental autonomy interest . . . ." *Id.* at 495 n.6, 495 N.E.2d at 343 n.6, 504 N.Y.S. 2d at 80 n.6. Specifically, the court maintained that the appropriate constitutional inquiry was to "balance the individual's liberty interest against the State's asserted compelling need on the facts of each case to determine whether such medication may be forcibly administered." *Id.* at 498, 495 N.E.2d 344, 504 N.Y.S.2d at 81.

194. *Id.* at 495 n.6, 495 N.E.2d at 343 n.6, 605 N.Y.S.2d at 80 n.6.

In the absence of these type of situations, there must be a judicial determination that the patient lacks the requisite mental capability for giving consent.[195] The determination is to be made by the judiciary, not by a medical professional.[196]

The *Rivers* court determined that administrative determinations do not adequately safeguard the patient's fundamental liberty interest guaranteed by Article 1, section 6 of the New York State Constitution.[197] Determination of capacity to make informed and reasonable consent must be made at a judicial hearing and the patient should be afforded legal representation.[198] However, the *Rivers* court pointed out, absent legislation to the contrary and the patient's clear intent, surrogates may not decide that a patient's health has deteriorated to the point where treatment is to be discontinued and the patient should be allowed to die.[199]

The Appellate Division, in *T.D.*, rejected the defendants' argument that a surrogate may make treatment decisions in research cases.[200] The court maintained that "substantive and procedural safeguards should be provided to these potential [greater than minimum risk non-therapeutic] research patients as are provided to patients in life-sustaining treatment settings."[201] It pointed out that the problem with New York's mental health regulations is that once the patient is deemed incapable of rendering valid consent, there are instances where the patient's

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195. *Id.* at 497, 495 N.E.2d at 344, 504 N.Y.S.2d 81.

196. *Id.* at 496, 495 N.E.2d at 343, 504 N.Y.S.2d at 80.

197. *Id.* at 498, 495 N.E.2d at 344, 504 N.Y.S.2d at 81. (holding that "the regulations do not articulate the standards to be followed or criteria to be considered at each stage of the administrative process, i.e., what the need is for the particular drug, whether a particular drug is the least intrusive, whether it is capable of producing the least serious side effects, and the proper length of its use.").

198. *Id.* at 497, 495 N.E.2d at 344, 504 N.Y.S.2d at 81.

199. *Id. See generally*, People v. Eulo, 63 N.Y.2d 341, 357, 472 N.E.2d 286, 296, 482 N.Y.S.2d 436, 446 (1984).

200. *T.D.*, 650 N.Y.S.2d at 191.

201. *Id.*

objection to participation in the research may be overridden.[202] These various provisions neither entitle the patient to notice that their objection is being overridden, nor do they provide for an adequate opportunity to seek a review of the psychiatrist's determination.[203] Moreover, the court points out that, because the "benefit" is left undefined in the regulations, "the benefit while required to be important to the health or well-being of the adult or minor patient, is not required to be a product of the research procedures or even related to the psychiatric condition presented by the patient."[204] Even with new medical advancements in the field of psychiatric drugs, the incompetent patients' rights must be protected against greater than minimum risk studies through constitutionally mandated procedures enacted by appropriate administrative agencies.[205]

In conclusion, the Appellate Division, First Department, found that lack of notice may lead to the patient not being aware that he/she is involved in the research.[206] Moreover, the lack of administrative and judicial review procedures established by OMH in cases of "non-therapeutic greater than minimal risk experimentation" failed to protect the patient's constitutionally guaranteed due process rights under the Federal and New York State Constitutions.[207]

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202. *Id.* at 193. *See, e.g.*, N.Y. COMP. CODES R. & REGS. tit. 14, § 527.10(e)(2)(viii) (1995) (providing instances for overriding the patient's objection in cases where "a psychiatrist who is not associated with the research finds and documents that . . . the research holds out a prospect of direct benefit that is important to the health or well-being of the patient . . . ."); N.Y. COMP. CODES R. & REGS. tit. 14, § 527.10(e)(3)(v) (1995) (providing that "[a] child's objection . . . must be honored, except when a child's psychiatrist who is neither employed by the facility nor associated with the research, finds . . . the research . . . holds out a prospect of direct benefit, that is important to the health or well-being of the child . . . .").

203. *T.D.*, 650 N.Y.S.2d at 193.

204. *Id.*

205. *Id.* at 194.

206. *Id.* at 191.

207. *Id.* at 192.